WE CLAIM:

1. A sensor control unit comprising:

a housing adapted for placement on skin and adapted to receive a portion of an electrochemical sensor having a plurality of contact pads;

a plurality of conductive contacts disposed on the housing and configured for coupling to the plurality of contact pads on the sensor; and

a transmitter disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using the sensor.

2. The sensor control unit of claim 1, further comprising adhesive for adhering the sensor control unit to skin.

3. The sensor control unit of claim 1, further comprising a mounting unit adapted for coupling with the housing.

4. The sensor control unit of claim 3, wherein the mounting unit is configured for placement between the housing and the skin of the patient.

5. The sensor control unit of claim 3, wherein adhesive is disposed on a surface of the mounting unit for adhering the mounting unit and housing to the skin of the patient.

6. The sensor control unit of claim 3, further comprising a support structure disposed on the mounting unit for aligning the contact pads of the sensor with the conductive contacts of the sensor control unit.

7. The sensor control unit of claim 3, further comprising an opening in the mounting unit configured for guiding insertion of the electrochemical sensor into the patient.

8. The sensor control unit of claim 1, wherein the housing comprises a base and a cover.

9. The sensor control unit of claim 8, wherein the base and cover are configured to form a water resistant seal when coupled.

10. The sensor control unit of claim 1, wherein the housing is water resistant.

11. The sensor control unit of claim 1, wherein the conductive contacts are disposed on an interior surface of the housing.

12. The sensor control unit of claim 11, wherein the housing comprises a port adapted for penetration by the sensor.

13. The sensor control unit of claim 1, wherein the plurality of conductive contacts are disposed on an exterior surface of the housing.

14. The sensor control unit of claim 1, wherein a volume of the housing is about 10 cm^3 or less.

15. The sensor control unit of claim 1, wherein a height of the housing is about 0.7 cm or less.

16. The sensor control unit of claim 1, wherein a weight of the housing is about 90 grams or less.

17. The sensor control unit of claim 1, further comprising a battery disposed in the housing.

18. The sensor control unit of claim 17, wherein the battery is sealed within the housing of the sensor control unit.

19. The sensor control unit of claim 17, wherein the battery is removable from the housing.

20. The sensor control unit of claim 1, further comprising an alarm to indicate at least one of hypoglycemia, impending hypoglycemia, hyperglycemia, or impending hyperglycemia.

21. The sensor control unit of claim 20, further comprising a switch for deactivating the alarm.

22. The sensor control unit of claim 21, wherein the switch is a reed switch, a Hall effect switch, or a gigantic magnetic ratio switch.

~~23.~~ 22. The sensor control unit of claim 20, wherein the alarm produces an audible signal when activated.

~~24.~~ 23. The sensor control unit of claim ~~23~~ 22, wherein a loudness of the alarm increases over time when the alarm is activated.

25. The sensor control unit of claim 20, wherein the alarm produces an electrical shock when activated.

~~26.~~ 24. The sensor control unit of claim 20, wherein the alarm produces a vibration when activated.

25.
~~27.~~ The sensor control unit of claim 20, wherein the alarm is configured to indicate at least two of hypoglycemia, impending hypoglycemia, hyperglycemia, or impending hyperglycemia.

26.
~~28.~~ The sensor control unit of claim 1, further comprising a receiver disposed in the housing.

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~~29.~~ The sensor control unit of claim 1, further comprising a processing circuit disposed in the housing and coupled to the conductive contacts, the processing circuit is configured for determining a level of an analyte from a signal generated by the sensor.

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~~30.~~ The sensor control unit of claim ~~29~~, wherein the processing circuit is configured for determining the level of the analyte in blood from a sensor that is subcutaneously implanted in the patient.

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~~31.~~ The sensor control unit of claim ~~29~~, wherein the processing circuit is configured for adjusting the data for temperature using a signal from a temperature probe of the sensor.

32. The sensor control unit of claim 1, wherein the transmitter is configured for transmitting an identification code with the data.

30.
~~33.~~ The sensor control unit of claim 1, wherein the plurality of conductive contacts of the sensor control unit comprise conductive carbon.

34. The sensor control unit of claim 1, wherein the transmitter includes an open loop modulation system for transmitting data obtained using the sensor, the open loop modulation system further comprising:

a phase-locked loop circuit for locking a signal carrying the data and having a center frequency at a predetermined transmit frequency, the signal being prevented from drifting in excess of a predetermined threshold;

a totalizer, operatively coupled to the phase-locked loop, for determining the status of the center frequency, the totalizer monitoring the center frequency, comparing the monitored center frequency to a threshold, and generating a control signal when the monitored frequency approaches the threshold; and

a loop control, operatively coupled to the totalizer, for detecting a lock condition of the phase-locked loop and for opening and closing the phase-locked loop in response to the control signal, the loop control closing the loop when the totalizer detects that the monitored frequency is approaching the threshold.

35. The sensor control unit of claim 34, wherein the open loop modulation system further comprises a modulation controller for generating a modulation signal and applying the modulation signal to the phase-locked loop.

36. The sensor control unit of claim 34, wherein the phase-locked loop remains open when the center frequency does not approach the threshold, the threshold indicating that the signal is within a bandwidth of a receiver.

37. The sensor control unit of claim 34, wherein the open loop modulation system sends a stand-by signal to the receiver when the center frequency approaches the threshold.

38. The sensor control unit of claim 34, wherein the phase-locked loop is opened prior to the generation of the modulating signal.

39. The sensor control unit of claim 34, wherein the open loop modulation system further comprises a transmitter amplifier for amplifying the signal carrying the data to ensure adequate output signal power.

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~~40.~~ The sensor control unit of claim 1, further comprising a data storage unit disposed in the housing for keeping data for a period of time.

41. The sensor control unit of claim 1, wherein the transmitter is configured for encrypting the data.

42. The sensor control unit of claim 1, wherein the transmitter further comprises circuitry for changing transmission frequencies to reduce crosstalk with other transmitters.

43. The sensor control unit of claim 1, further comprising a current-to-voltage converter coupled to at least two of the conductive contacts.

44. The sensor control unit of claim 42, wherein the current-to-voltage converter comprises a capacitor, a first set of switches coupled to the capacitor for charging the capacitor by connecting the capacitor to the conductive contacts when the first set of switches is closed, a second set of switches coupled to the capacitor for discharging the capacitor when the second set of switches is closed, and a clock generator coupled to the first and second set of switches for generating a clock signal to alternate between a first position with the first set of switches closed and the second set of switches open and a second position with the first set of switches open and the second set of switches closed, the clock signal having a frequency that provides a frequency-dependent impedance to the capacitor.

32.

~~45.~~ A sensor assembly, comprising:

a sensor having a substrate, at least one recessed channel formed in a surface of the substrate, conductive material disposed in the at least one recessed channel to form at least one working electrode and an individual contact pad for each of the at least one working electrodes; and

a sensor control unit for placement on a skin of an animal, the sensor control unit including

a housing having a port through which the sensor penetrates the housing, and

a plurality of conductive contacts disposed in the housing and configured for coupling with the contact pads of the sensor.

46. A sensor assembly, comprising:

a sensor comprising a flexible substrate with at least one working electrode, at least one counter electrode, and at least one contact pad coupled to each of the working and counter electrode(s); and

a sensor control unit comprising

a housing adapted for placement on skin;

a plurality of conductive contacts disposed on the housing and configured for coupling to the contact pads of the sensor; and

a transmitter disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using the sensor.

~~47~~. A sensor assembly, comprising:

a sensor comprising at least one working electrode and at least one contact pad coupled to the at least one working electrode; and

the sensor control unit of claim 1.

~~48~~. The sensor assembly of claim ~~47~~, wherein the plurality of conductive contacts, the plurality of contact pads, or both comprise conductive carbon.

~~49~~. The sensor assembly of claim ~~48~~, wherein a signal generated by corrosion of the plurality of conductive contacts and the plurality of contact pads when immersed in a 1 mM NaCl solution is 3% or less of a signal generated by the working

electrode when exposed to an analyte having a concentration within an expected physiological range.

37. 35,
~~50.~~ The sensor assembly of claim ~~48~~, wherein a signal generated by corrosion of the plurality of conductive contacts and the plurality of contact pads when immersed in a 100 mM NaCl solution is 3% or less of a signal generated by the working electrode when exposed to an analyte having a concentration within an expected physiological range.

38. 34,
~~51.~~ The sensor assembly of claim ~~47~~, further comprising a mounting unit adapted for coupling with the housing.

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52. An analyte monitoring system comprising:

a sensor comprising at least one working electrode and at least one contact pad coupled to the at least one working electrode;

the sensor control unit of claim 1; and

a display unit comprising a receiver for receiving data from the sensor control unit, and a display coupled to the receiver for displaying an indication of the level of an analyte.

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~~53.~~ The analyte monitoring system of claim ~~52~~, further comprising a mounting unit adapted for coupling with the housing.

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54. The analyte monitoring system of claim 52, wherein the sensor control unit further comprises a receiver disposed in the housing and the display unit further comprises a transmitter for transmitting to the receiver of the sensor control unit.

55. The analyte monitoring system of claim 52, wherein the display unit further comprises an analyzer coupled to the display and the receiver for analyzing data from the receiver and providing analyzed data to the display.

~~56~~ 43. The analyte monitoring system of claim ~~52~~ 39, wherein the display unit further comprises a battery coupled to the receiver and display.

~~57~~ 44. The analyte monitoring system of claim ~~52~~ 39, wherein the display unit further comprises an input device coupled to the display.

~~58~~ 45. The analyte monitoring system of claim ~~52~~ 39, further comprising a calibrator for providing a calibration value to at least one of the display unit and the sensor control unit.

~~59~~ 46. The analyte monitoring system of claim ~~58~~ 45, wherein the calibrator is coupled to the receiver of the display unit for providing the calibration value to the sensor control unit.

~~60~~ 47. The analyte monitoring system of claim ~~58~~ 45, wherein the calibrator provides a calibration value using 1 microliter or less of body fluid.

~~61~~ 48. The analyte monitoring system of claim ~~58~~ 45, wherein the calibrator comprises a device configured for non-invasive optical assay of analyte.

~~62~~ 49. The analyte monitoring system of claim ~~52~~ 39, wherein the display unit is portable.

~~63~~ 50. The analyte monitoring system of claim ~~62~~ 49, wherein the display unit is configured for wearing on a piece of clothing.

~~64~~ 51. The analyte monitoring system of claim ~~62~~ 49, further comprising a secondary display unit having a power cord for connecting to an electrical outlet, a

receiver for receiving data transmitted by the transmitter, and a display coupled to the receiver for displaying the level of the analyte.

65. The analyte monitoring system of claim 64, wherein the display unit and the secondary display unit are configured for exchanging data.

66. The analyte monitoring system of claim 52, wherein the display unit is configured for connection to an electrical outlet.

67. The analyte monitoring system of claim 66, wherein the display unit further comprises at least one of a lamp, a radio, a clock, an interface to a telephone system, an interface to a computer, or a battery backup system.

68. The analyte monitoring system of claim 52, wherein the display unit further comprises an alarm configured for activation if a signal from the transmitter of the sensor control unit is not received with a predetermined time interval.

69. The analyte monitoring system of claim 52, wherein the display unit comprises a pager receiver for receiving pages from an external paging system.

70. The analyte monitoring system of claim 69, wherein the display unit comprises a pager transmitter for sending pages to the external paging system, wherein the pager transmitter is activated when at least one of hypoglycemia, impending hypoglycemia, hyperglycemia, or impending hyperglycemia is indicated.

71. The analyte monitoring system of claim 52, wherein the display unit is configured for coupling to an external download device to transfer data from the display unit.

59. 39.
72. The analyte monitoring system of claim 52, further comprising at least one alarm disposed in the display unit and configured to indicate when a level of an analyte exceeds a threshold level.

60. 59.
73. The analyte monitoring system of claim 72, wherein the alarm is configured to indicate when a level of an analyte is near a threshold level.

61. 60.
74. The analyte monitoring system of claim 73, wherein the alarm is configured to indicate at least one of hypoglycemia, impending hypoglycemia, hyperglycemia, or impending hyperglycemia.

62. 61.
75. The analyte monitoring system of claim 74, wherein the alarm is configured to indicate impending hypoglycemia and is deactivated if an impending hypoglycemia condition does not exist.

63. 61.
76. The analyte monitoring system of claim 74, wherein the alarm is configured to indicate hypoglycemia and is only manually deactivatable.

64. 61.
77. The analyte monitoring system of claim 74, wherein the alarm is configured to indicate hypoglycemia and the alarm, when activated, produces an audible signal that increases in loudness over time.

65. 59.
78. The analyte monitoring system of claim 72, wherein the analyte monitoring system comprises at least two alarms, each alarm producing an audible signal, wherein the signals of the at least two alarms are distinguishable.

66. 39.
79. The analyte monitoring system of claim 52, further comprising a processing circuit in the display unit, the processing circuit being configured to analyze patient-specific data from multiple episodes to predict a patient's response to future episodes.

80. The analyte monitoring system of claim 79, wherein the one or more physiological characteristics comprises a response to a treatment.

81. The analyte monitoring system of claim 80, wherein the analyte is glucose and the treatment is an administration of insulin.

82. The analyte monitoring system of claim 80, wherein the display unit further comprises an input device for indicating when a treatment is administered.

83. The analyte monitoring system of claim 79, wherein the processing circuit is configured to determine a drug administration protocol in response to the physiological characteristic.

84. The analyte monitoring system of claim 79, wherein the physiological characteristic is a dosage dependence of a response to a drug.

85. The analyte monitoring system of claim 79, wherein the display unit further comprises an input device for indicating when food has been injested.

86. The analyte monitoring system of claim 85, where the input device is configured for indicating an approximate caloric content of the food.

87. The analyte monitoring system of claim 52, further comprising a temperature measurement device to correct data obtained from the sensor.

88. The analyte monitoring system of claim 87, wherein the temperature measurement device comprises a temperature probe disposed on the substrate.

89. The analyte monitoring system of claim 52, wherein the analyte monitoring system further comprises a drug administration system which dispenses a drug based on the level of the analyte.

90. The analyte monitoring system of claim 89, wherein the drug administration system comprises a receiver for receiving data from at least one of the sensor control unit or display unit to direct dispensing of the drug.

91. The analyte monitoring system of claim 89, wherein the drug administration system comprises at least one of a needle, syringe, pump, catheter, inhaler, or transdermal patch to administer the drug.

92. The analyte monitoring system of claim 89, wherein the drug is insulin.

93. The analyte monitoring system of claim 52, further comprising a repeater unit to boost transmission of data from the on-skin sensor control unit to the display unit.

94. An insertion kit for inserting an electrochemical sensor into a patient, the insertion kit comprising:

an inserter comprising a portion having a sharp, rigid, planer structure adapted to support the sensor during insertion of the electrochemical sensor; and

an insertion gun having a port configured to accept the electrochemical sensor and the inserter, a driving mechanism for driving the inserter and electrochemical sensor into the patient, and a retraction mechanism for removing the inserter from the patient while leaving the sensor within the patient.

95. The insertion kit of claim 94, wherein the insertion gun further comprises a cocking mechanism to maintain the inserter and electrochemical sensor in a cocked position prior to insertion into the patient, and a release mechanism to release the

inserter and electrochemical sensor from the cocked position and permit the driving mechanism to drive the inserter and electrochemical sensor into the patient.

96. The insertion kit of claim 94, further comprising an electrochemical sensor for insertion into the patient using the inserter and insertion gun.

97. The insertion kit of claim 96, wherein the electrochemical sensor includes a barb to facilitate retention of the sensor within the patient.

98. The insertion kit of claim 96, wherein the electrochemical sensor is flexible.

99. The insertion kit of claim 94, wherein the insertion gun and inserter are configured to insert the electrochemical sensor into the patient at a depth of between about 2 to 12 mm.

100. The insertion kit of claim 94, wherein the insertion gun and inserter are configured to insert the electrochemical sensor into the patient at an angle between about 15° to 60° relative to a surface of the patient.

101. The insertion kit of claim 94, wherein the inserter has a cross-sectional width of 1 mm or less.

102. The insertion kit of claim 94, wherein the inserter has a cross-sectional height of 1 mm or less.

103. The insertion kit of claim 94, wherein the inserter gun is configured to mate with a mounting base of a sensor control unit.

104. A method of using an electrochemical sensor, the method comprising:

adhering a mounting unit to a skin of a patient;

aligning an insertion gun with a port on the mounting unit, the insertion gun having an electrochemical sensor disposed therein;

inserting an electrochemical sensor into the skin of the patient using the insertion gun;

removing the insertion gun;

mounting a housing of a sensor control unit on the mounting base; and

coupling a plurality of conductive contacts disposed on the housing with a plurality of contact pads disposed on the electrochemical sensor.

105. The method of claim 104, wherein the plurality of conductive contacts and the plurality of contact pads are coupled when the housing is mounted on the mounting base.

106. The method of claim 104, further comprising applying a skin protecting material to the skin prior to adhering the mounting unit.

107. The method of claim 104, wherein the electrochemical sensor is disposed in a sharp, rigid inserter, the sensor being released from the inserter after insertion.

108. A method for detecting failures in an implanted analyte-responsive sensor, the method comprising:

implanting an analyte-responsive sensor into a patient, the analyte-responsive sensor comprising N working electrodes, where N is an integer and is two or greater, and a common counter electrode;

obtaining a signal generated at one of the N working electrodes and a signal generated at the common counter electrode; and

determining failure of the analyte-responsive sensor if the signal from the common counter electrode is not N times the signal from the one of the N working electrodes, within a predetermined threshold limit.

109. A method of calibrating an electrochemical sensor implanted in a patient and comprising one or more working electrodes, the method comprising:

(a) generating a signal from each of the one or more working electrodes;

(b) determining if each of conditions (1) to (3) are met

(1) the signals from each of the one or more working electrodes differ by less than a first threshold amount;

(2) the signals from each of the one or more working electrodes are within a predetermined range, and

(3) a rate of change of the signals from each of the one or more working electrodes is less than a second threshold amount.

(c) determining a calibration value by assaying a calibration sample of a patient's body fluid; and

(d) relating the calibration value to at least one of the signals from the one or more working electrodes if the conditions in step (b) are met.

110. The method of claim 109, further relating the calibration value to at least one of the signals from the one or more working electrodes only if a predetermined period of time has passed since the sensor was implanted in the patient.

111. The method of claim 109, further relating the calibration value to at least one of the signals from the one or more working electrodes only if a signal from a temperature probe disposed on the electrochemical sensor is within a predetermined range.

112. The method of claim 111, further comprising measuring a conductivity of a body fluid using the temperature probe to determine a temperature of the body fluid.

113. A method for monitoring a level of an analyte using the analyte monitoring system of claim 52, the method comprising:

inserting the sensor into skin of a patient;

attaching the sensor control unit to the skin of the patient;

coupling a plurality of conductive contacts disposed in the sensor control unit to a plurality of contact pads disposed on the sensor;

collecting data, using the sensor control unit, regarding a level of an analyte from signals generated by the sensor;

transmitting the collected data to the display unit; and

displaying an indication of the level of the analyte on the display of the display unit.

114. The method of claim 113, wherein collecting data comprises generating signals from the sensor and processing the signals into data.

115. The method of claim 113, wherein the data comprises the signals from the sensor.

116. The method of claim 113, further comprising activating an alarm if the data indicates an alarm condition.

117. The method of claim 113, further comprising administering a drug in response to the data.

118. The method of claim 113, further comprising obtaining a calibration value from a calibration device to calibrate the data.

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119. The method of claim 118, wherein the calibration device is coupled to the display unit.

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120. The method of claim 119, further comprising transmitting the calibration value from a transmitter in the display unit to a receiver in the sensor control unit.

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